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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,294	10/31/2003	James M. Zavislan	ML-0434DIV	1407

7590 01/25/2005

South Winton Court
Suite 204
3136 Winton Road South
Rochester, NY 14623

EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/698,294	Applicant(s) ZAVISLAN ET AL.	
	Examiner Shawna J. Shaw	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/31/2003, 1/26/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01262004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Confocal microscopy which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification does not address how to image one or more tissue sections without the aid of a confocal scanning microscope.
2. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cellular surgery using confocal microscopy, does not reasonably provide enablement for imaging the tissue section(s) with another modality. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. See e.g., title, specification page 1 lines 9-10 and page 12 lines 23-24.

Claim Interpretation/Definitions

For examination purposes, the examiner understands "section" to mean 'a small region of tissue' (specification, p. 2 lines 17-18) 'composed of one or more cells'

(specification page 3 lines 9-10) and described in terms of "x-y" coordinates (specification, page 6 lines 11-14).

For examination purposes, the examiner understands "treating" to include *inter alia*, heating, ablating, photo-chemically or photo-mechanically "effecting" tissue, or photo-activating a drug (specification, page 8 lines 3-6).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Zavislan (WO 95/03089).

Regarding claims 7-9, Zavislan et al. teach focused treating and imaging/monitoring of one or more sections of tissue (inherently including one or more cells) wherein a CCD is used to detect the reflected illuminating laser beam. See generally claims 1-35. Further regarding claim 10, Zavislan et al. disclose optics (42, 44, see e.g., fig. 3).

4. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Denk et al. of record.

Denk et al. teach confocal imaging/monitoring (fig. 1, col. 5 lines 26-29) and (photo-chemical, photoactivation, photolysis) treatment of sections of tissue on a cellular

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basis (as also evidenced by 6,042,603 col. 3 lines 11-16, citing the special confocal laser scanning and photo-activation microscope of Denk et al).

5. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nudelman et al. of record.

Nudelman et al. disclose imaging/monitoring treatment of sections of tissue on a cellular basis using a confocal imaging system (12, col. 7 line 25 – col. 8 line 2), laser beam for therapy (24), and coupling optics (28). See figures 3 and 8 and col. 8 lines 40-68.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratzer et al. of record.

Regarding claims 7-9, Kratzer et al. teach treating and imaging/monitoring select cells with the aid of one or more laser beams. See col. 3 lines 17-46 and col. 5 line 51 – col. 6 line 29. Kratzer et al. differs from the claimed invention in that cells in blood are treated instead of cells in tissue. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use the method to treat cells in either tissue or blood because Applicant has not disclosed that treating cells in tissue provides an advantage, is used for a particular purpose, or solves a stated problem (see specification, page 9 lines 17-19 - where cells in blood moving through capillaries are treated). One of ordinary skill in the art, furthermore, would have expected Applicant's method to perform equally well with the invention of Kratzer et al. because both are able to perform treatment on one or more cell(s) and also because the context of the cell (tissue, blood) is immaterial on the cellular level.

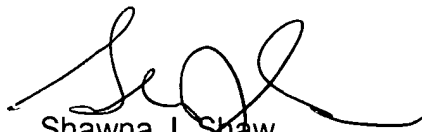
Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (571) 272-4743. The examiner can normally be reached on 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw
Primary Examiner
Art Unit: 3737
01/21/2005